UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

NOVOTECH (AUSTRALIA) PTY LIMITED, an Australian proprietary limited company, Plaintiff, v. SURECLINICAL INC., a Nevada corporation, Defendant.	No. 2:22-cv-01259-JAM-AC **ORDER GRANTING PLAINTIFF NOVOTECH (AUSTRALIA) PTY LIMITED'S MOTION FOR PRELIMINARY INJUNCTION**

The matter before the Court is Novotech (Australia) Pty Limited's ("Novotech") motion for preliminary injunction. See Mot. for Preliminary Inj. ("Mot."), ECF No. 18. SureClinical Inc.'s ("SureClinical") opposed the motion. See Opp'n, ECF No. 19. Novotech replied. See Reply, ECF No. 21.[1]

I. FACTUAL ALLEGATIONS AND PROCEDURAL BACKGROUND

As the facts are already known to the parties, the Court repeats them only as necessary to explain its decision.

[1] This motion was determined to be suitable for decision without oral argument. E.D. Cal. L.R. 230(g). The hearing was scheduled for November 1, 2022.

Novotech is a clinical research organization, which facilitates and manages clinical trials for biotechnology, pharmaceutical, and research clients. Mot. at 4. Part of Novotech's services includes maintaining the electronic Trial Master File ("eTMF") for each clinical trial they conduct for a client to ensure that the trial is safe, sound, and in strict compliance with the FDA. Id. Novotech contends that continuous access to eTMFs is essential to the viability of clinical trials and that even temporary loss of access can result in: (1) regulatory violations and citations; (2) rejection of the trial by regulators; (3) threats to the safety of patient-participants; and (4) contractual breaches that damage business relationships and reputations. Id. at 4. SureClinical licenses its suite of cloud-based software applications to assist in the operation of clinical trials, including the storage and management of eTMFs. Id. In 2014, SureClinical and Novotech entered into a contract, the Master Subscription Agreement ("MSA"), where SureClinical agreed to license its software to Novotech for use in Novotech's clinical trials and the management of its eTMFs. Id. at 5; MSA, Exhibit 3 to Declaration of Rajiv Dharnidharka, ECF No. 13. Novotech alleges that its access to SureClinical's platform was contingent upon payment of an annual fee and a monthly per-trial fee. Mot. at 5. SureClinical alleges that access to its software platform is based on a subscription fee and a user fee. Opp'n at 2. Novotech contends that the MSA permitted access for: (1) Novotech's employees, agents, representatives, consultants, and independent contractors; (2) Novotech's clients; (3) Novotech's clients'

agents, employees, representatives, consultants, and independent contractors; (4) any other persons or entities Novotech bound to the MSA; and (5) the agents, employees, representatives, consultants, and independent contractors of those bound third parties. Mot. at 5. SureClinical alleges that Novotech contracted to use SureClinical's software solely for its internal use with a limited number of one hundred named users, as outlined in its supplemental Order Form, and that Novotech expressly turned down the right to use and distribute SureClinical's platform outside of Novotech with users not affiliated with Novotech. Opp'n at 4-5.

Novotech expressed its intention to not renew the MSA in February 2022 and to export its trial data off of SureClinical's platform to a new provider. Mot. at 5-6. Under the MSA, the contract term is set to expire on December 31, 2022. Id. at 5. Novotech alleges that SureClinical took several measures against Novotech following its stated intention to not renew the MSA, including: (1) impeding Novotech's ability to export eTMFs off of SureClinical's platform; (2) demanding that SureClinical pay millions of dollars in additional fees; (3) unilaterally modifying the terms and fee structure of the MSA to exclude previously covered users; and (4) demanding that Novotech commit to an audit of its financial records. Id. at 6-7. Novotech further contends that on November 3, 2022 SureClinical cut off Novotech and its users from SureClinical's platform; they are no longer able to access and manage their eTMF's and other trial data. Second Supplemental Declaration of Michael F. Donner ("Supp. Decl."), ECF No. 27. SureClinical claims that it only

cut off access for unauthorized, external accounts on November 3. Objection and Request to Strike, ECF No. 27, at 1. SureClinical further contends that its limit on exports to one per day occurred in the summer of 2021 following a near complete system collapse after one of its clients attempted to export fifty studies off of the platform at one time. Opp'n at 5. In order to avoid another near collapse and because users tended to average one study export per month, SureClinical modified its platform to allow only one study export per day for all of its users; Novotech was promptly notified of this change and spent six months testing the updated version of the platform without objection and had its requests for accommodations met, when feasible. Id. at 5-6. SureClinical contends that Novotech had ample time to export its clinical data from SureClinical's platform from the day Novotech notified SureClinical of its decision to not renew the MSA and that for SureClinical to allow unlimited daily exports again for Novotech would cost the company approximately $2.7 million. Id. at 6. SureClinical argues that Novotech breached the terms of the MSA by (1) exceeding the scope of its license by granting access to the platform to more than the authorized one hundred internal users and (2) evading the audit authorized under the terms of the MSA; Novotech's injunction is simply a way to distract the Court from its misconduct. Id. at 7-8.

On July 15, 2022, Novotech filed the operative complaint against SureClinical, alleging breach of contract and seeking declaratory relief from the Court regarding the parties' respective rights and obligations under the MSA. See Compl.,

ECF. No. 1. SureClinical filed a first amended answer and counterclaim alleging breach of contract and copyright infringement and seeking declaratory relief on the disputed terms of the MSA. See First Amend. Answer and Counterclaim, ECF. No. 12. Several weeks later, Novotech filed this motion for preliminary injunction seeking to: (1) prohibit SureClinical from impeding or terminating the access of Novotech, its clients, its client's agents, and regulatory authorities to SureClinical's platform; and (2) prohibit SureClinical from imposing or maintaining any restrictions on Novotech's ability to export its clients' data and documents off of SureClinical's platform. Mot. at 1. SureClinical opposes the motion. See Opp'n. Novotech replied. See Reply.

II. OPINION

A. Legal Standard

A preliminary injunction is an "extraordinary remedy" that a court may award only "upon a clear showing that the petitioner is entitled to such relief." Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, 22 (2008). To obtain a preliminary injunction, a petitioner must demonstrate that: (1) they will likely succeed on the merits, (2) they will suffer irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in their favor, and (4) an injunction is in the public interest. Boardman v. Pacific Seafood Group, 822 F.3d 1011, 1020 (9th Cir. 2016) (quoting Winter, 555 U.S. at 20).

Post-Winter, the Ninth Circuit kept a "sliding scale approach" to preliminary injunctions known as the "serious questions test." Alliance for the Wild Rockies v. Cottrell, 632

F.3d 1127, 1131 (9th Cir. 2011). Under this approach, a "likelihood" of success is not an absolute requirement. Id. at 1132. "Rather, serious questions going to the merits and a hardship balance that tips sharply toward the [petitioner] can support issuance of an injunction, assuming the other two elements of the Winter test are also met." Drakes Bay Oyster Co. v. Jewell, 747 F.3d 1073, 1085 (9th Cir. 2014). "Serious questions" under this approach constitutes "questions which cannot be resolved one way or the other at the hearing on the injunction," but which suggest that the petitioner has a "fair chance" of prevailing. Republic of the Philippines v. Marcos, 862 F.2d 1355, 1362 (9th Cir. 1988).

B. Analysis

1. Motion for Preliminary Injunction

a. Factor One: Success on the Merits

Novotech argues that it is likely to succeed on its breach of contract claims because SureClinical breached and repudiated its contractual duties under the MSA. Mot. at 13. Novotech states that, under the MSA, SureClinical agreed to provide access to its platform until December 31, 2022 and Novotech has prepaid all of its annual fees for these services and has offered to prepay its future monthly fees. Id. at 14. Novotech claims that, despite its payments and offer to prepay, SureClinical committed an anticipatory breach of its duty to provide Novotech and its users with continuous access to SureClinical's platform when it notified Novotech that it would terminate access on November 3, 2022 unless Novotech agreed to additional terms outside of the MSA, including: (1) assenting to SureClinical's

modification of the MSA's use terms and fee structure; (2) paying millions of dollars in extra fees to SureClinical based on these modifications; and (3) complying with an audit requested by SureClinical under Section 11.8 of the MSA. Id. at 14. SureClinical also allegedly breached its duty of good faith and fair dealing by modifying its software to limit Novotech's ability to transfer its clients' eTMFs off of SureClinical's platform. Id. These breaches will force Novotech to extend the MSA and pay SureClinical millions of dollars in unwarranted license and service fees. Id.

SureClinical responds that Novotech fails to support its breach of contract claims with any section of the MSA or the applicable Order Form. Opp'n at 14. SureClinical contends that Novotech has failed to sufficiently allege express or implied repudiation to support its anticipatory breach allegation because SureClinical's decision to cut off access on November 3, 2022 applies only to unauthorized users; SureClinical's right to deny access to these unauthorized users is consistent with its authority under Section 2.7 of the MSA. Id. at 14-15. As for the duty of good faith and fair dealing claim, SureClinical contends that state law does not permit this duty to impose substantive terms and conditions beyond the express terms of the MSA and Order Form; neither document refers to free, unlimited export capabilities for platform users, so it would be inappropriate for the implied duty of good faith and fair dealing to impose such a responsibility on SureClinical. Id. at 15-16. SureClinical argues that the express terms of the MSA and Order Form allow SureClinical to change its platform and charge an

hourly rate for services not expressly stated in writing, which applies to the custom export services that Novotech is requesting. Id.

The Court finds that Novotech has raised serious questions on the merits of its breach of contract claims, specifically with respect to SureClinical's express notice to Novotech that SureClinical would cut off access to its platform to alleged unauthorized users on November 3, 2022. A preliminary injunction is appropriate where a petitioner shows "serious questions going to the merits and a hardship balance that tips sharply toward" their favor. Drakes Bay, 747 F.3d at 1085. Serious questions are those "which cannot be resolved one way or the other at the hearing on the injunction," but which suggest that the petitioner has a "fair chance" of prevailing. Republic of the Philippines, 862 F.2d at 1362. A cause of action for breach of contract requires a showing of: (1) a contract; (2) performance by petitioner or excuse for non-performance; (3) breach; and (4) damage to petitioner from the breach. Acoustics, Inc. v. Trepte Constr. Co., 14 Cal. App. 3d 887, 913 (Ct. App. 1971). A contract is to be interpreted solely from the written provisions of the contract, if possible. Foster-Gardner, Inc. v. Nat'l Union Fire Ins. Co., 18 Cal. 4th 857, 868 (1998). "If the contractual language is clear and explicit, it governs." Id. If an alleged ambiguity in the contract is not resolved by the language or context of the contract, the ambiguity is "generally construed against the party who caused the uncertainty to exist." Id. Repudiation, also known as "anticipatory breach," occurs when the contract is repudiated by the promisor

before the promisor's performance under the contract is due. See Taylor v. Johnston, 15 Cal. 3d 130, 137 (1975). Novotech has sufficiently alleged (1) the existence of a contract between the parties, through the MSA and Order Form, (2) performance of the contract by Novotech, and (3) damages that would result if Novotech and its clients are unable to access SureClinical's platform and are forced to assent to SureClinical's demand to pay additional fees. While the Court does not find that Novotech has sufficiently alleged that SureClinical's notice cutting off access to unauthorized users on November 3 constitutes an anticipatory breach, it finds that there are serious questions concerning the distinction between authorized and unauthorized users that implicate Novotech's claim. The MSA defines authorized users as the "employees, representatives, consultants, or agents" of Novotech or any other legal entity for which Novotech is accepting the MSA's terms; the MSA contains no express limit on the number of authorized users. MSA at 3. While SureClinical asserts that the authorized users under the MSA's terms are limited to one hundred named users focused solely on Novotech's internal operations, the terms of the MSA are unclear as to (1) what constitutes internal operations and (2) how trial sponsors and federal regulators, who must have access to trial eTMFs to ensure federal compliance, are to be classified. Even SureClinical's reference to the Order Form to support its claim that it only authorized one hundred Novotech users to access the platform is unclear; the Order Form refers, in part, to "100 Ent. Named Users Std Adobe digital certs," in its line-item description but, on its face, the Order Form

provides no clarity on what that means or how it is to be applied to Novotech. Order Form, Exhibit 4 to Declaration of Rajiv Dharnidharka, ECF No. 13. This ambiguity is furthered by the context of the parties' eight-year continuous, contractual relationship, during which the issue of Novotech granting access to the platform to alleged unauthorized users was not brought up by SureClinical until shortly after Novotech expressed its decision to not renew the contract. In light of these contractual ambiguities, which must be construed against SureClinical as the party that created the MSA and Order Form, the Court finds that serious questions have been raised regarding Novotech's breach of contract claims and that Novotech has a fair chance of prevailing on these claims.

b. Factor Two: Irreparable Harm

Novotech alleges that it will suffer irreparable harm from SureClinical's cutting off its access to the SureClinical platform in the form of: (1) damaging the viability and success of Novotech's clinical trials and eTMFs currently on the platform; (2) delaying or preventing the approval of new drugs and devices; (3) preventing trial sponsors from being fully transparent with institutional review boards; (4) exposing Novotech to increased scrutiny from federal regulators; (5) exposing Novotech to legal liability to clients; (6) threatening the safety and privacy of clinical trial patients; and (7) a general risk to public health. Mot. at 9-12. Novotech also alleges that SureClinical's alleged slowing of Novotech's export capabilities will result in: (1) Novotech being forced to maintain its contractual relationship with SureClinical

until all files have been exported; (2) Novotech having to pay SureClinical millions of dollars in extorted fees; and (3) the delay or prevention of the approval of important drugs and medical devices. Id. at 13.

SureClinical responds that all of Novotech's claims must fail because they are speculative, self-inflected, and can be compensated with monetary damages. Opp'n at 16. SureClinical states that it has offered Novotech a $2.7 million custom service to assist Novotech with its eTMF exports, which Novotech has refused to agree to, even though Novotech could recover those costs if it succeeds in the underlying action. Id. at 16-17. SureClinical argues that Novotech's concerns relating to the viability of its clinical trials, regulatory scrutiny, legal liability, and public health are speculative because SureClinical has not threatened to delete any data and Novotech does not distinguish between the access privileges of authorized and unauthorized users; Novotech's one hundred authorized users that it contracted for will be unaffected, while the unauthorized users would lose access under the applicable terms of the MSA. Id. at 18-21. Also, Novotech does not support its claims with testimony from its trial sponsors, federal regulators, medical professionals, or trial patients who are allegedly relying on Novotech's trials. Id. As for Novotech's export capabilities, SureClinical claims that Novotech's alleged injury was self-inflicted because Novotech had notice of the export limit in April 2022 and did not proceed to consistently conduct eTMF exports despite the end of year deadline on the MSA. Id. at 22. SureClinical also notes that Novotech delayed filing its

injunction, which implies a lack of urgency and irreparable harm. Id. at 23.

The Court finds Novotech's argument persuasive. A petitioner "may not obtain a preliminary injunction unless they can show that irreparable harm is likely to result in the absence of the injunction." Cottrell, 632 F. 3d at 1135. "Indeed, suffering irreparable harm prior to a determination of the merits is perhaps the single most important prerequisite for the issuance of a preliminary injunction." See Nutrition Distribution LLC v. Lecheek Nutrition Inc., No. CV 15-1322-MWF (MRWx), 2015 WL 12659907 (C.D. Cal. June 5, 2015) (internal citations omitted). A petitioner must demonstrate "immediate threatened injury." Caribbean Marine Servs. Co. v. Baldrige, 844 F.2d 668, 674 (9th Cir. 1988). The Ninth Circuit has established that irreparable harm can include damage to a company's brand, reputation, or goodwill, particularly as they relate to standards of quality control and customer service; damage to one's competitive position and market share are also grounds for a finding of irreparable harm. Apple Inc. v. Psystar Corp., 673 F. Supp. 2d 943, 948–49 (N.D. Cal. 2009), aff'd, 658 F.3d 1150 (9th Cir. 2011); see also Regents of Univ. of California v. Am. Broad. Companies, Inc., 747 F.2d 511, 520 (9th Cir. 1984). Novotech has sufficiently alleged damage to (1) the viability of its clinical trials, (2) its reputation and goodwill with clients and federal regulators, and (3) the safety of its trial patients; also, these concerns have moved beyond speculation because of SureClinical's recent actions to restrict Novotech's access to its platform, so the harm is immediate. While the Court notes Novotech's delay in

pursuing injunctive relief, delay is not "particularly probative in the context of ongoing, worsening injuries" and is insufficient on its own to dismiss a claim of irreparable harm. Disney Enterprises, Inc. v. VidAngel, Inc., 869 F.3d 848, 866 (9th Cir. 2017). Therefore, Novotech has demonstrated irreparable harm absent an injunction.

c. Factor Three: Balance of the Equities

Novotech argues that the balance of equities tips sharply in its favor because SureClinical cutting off access to its platform before December 31, 2022 would result in considerable irreparable harm to Novotech, its clients, and the general public, which Novotech extensively described in the preceding section. Mot. at 15. Granting the injunction would maintain the status quo because SureClinical would be compelled to follow through with its contractual obligations, as it has done for the past eight years. Id. Novotech claims that SureClinical would not suffer any financial harm because Novotech has already paid what it owes under the MSA; should the Court find that SureClinical prevails on the merits of its claims, monetary damages would be adequate. Id.

SureClinical responds that it would face great hardship if it were compelled to write new code to accommodate Novotech's export demands and give platform access to unauthorized, non-paying third parties. Opp'n at 23. SureClinical argues that Novotech has failed to identify specific trials that would be harmed absent an injunction or a specific provision in the MSA that requires SureClinical to provide the free export services that Novotech is seeking. Id. SureClinical claims that the

issuance of Novotech's injunction would cost it over $2.7 million and would divert engineering resources away from other parts of the platform. Id. at 24. Also, granting access to unauthorized users adversely affects SureClinical's copyright protections and oversight capabilities, particularly because of Novotech's refusal to comply with the Section 11.8 audit. Id.

The Court finds that the balance of equities weighs sharply in favor of Novotech. A court must "balance the interests of all parties and weigh the damage to each" in determining the balance of the equities. CTIA-The Wireless Ass'n v. City of Berkeley, California, 928 F.3d 832, 852 (9th Cir. 2019) (citing Stormans, Inc. v. Selecky, 586 F.3d 1109, 1138 (9th Cir. 2009)). SureClinical, as the platformer through which Novotech continues to manage and operate a number of its clinical trials, has exclusive control over whether Novotech and its clients can access their trial eTMFs and documents, and SureClinical has recently demonstrated that it is prepared to exercise that control absent an injunction. It has been alleged that even temporary loss of access can result in considerable hardship to Novotech, including regulatory citations, rejection of clinical trials, threats to patient safety, and reputational damage, all of which shift the balance of equities in Novotech's favor. Also, issuance of the injunction will return the parties to the status quo with respect to access to the platform, considering the underlying action marks the first time in the parties' eight-year relationship that SureClinical has raised an issue regarding unauthorized users. SureClinical's concerns about the engineering costs of complying with the injunction and Novotech's

resistance to the Section 11.8 audit can be addressed by a monetary damages award in the underlying action and SureClinical's own pending motions for a preliminary injunction and stay.

d. Factor Four: Public Interest

Novotech argues that an injunction is in the public interest because the effects of SureClinical's threatened actions extend beyond Novotech to include its trial sponsors, trial patients, and the general public. Mot. at 15. SureClinical responds that the public interest goes against issuance of the injunction because: (1) the public has a strong interest in enforcing contracts and not imposing obligations inconsistent with express terms, which is what Novotech is requesting the Court do in this case; and (2) SureClinical's compliance with the injunction will require it to shift engineering resources away from other customers' trials to accommodate Novotech's needs. Opp'n at 24-25.

The Court finds that the public interest favors granting the injunction. Special consideration is given to the potential impact on nonparties by the issuance or denial of injunctive relief. League of Wilderness Defenders/Blue Mts. Biodiversity Project v. Connaughton, 752 F.3d 755, 766 (9th Cir. 2014). In this instance, the potential damage to trial sponsors, trial patients, and the general public if Novotech and its clients' clinical trials are interrupted or corrupted by SureClinical's threatened actions outweighs the burden on SureClinical's other clients, particularly in light of the parties' extensive business relationship and SureClinical's

exclusive control over its platform's functions and capabilities. The public's interest in enforcing the express terms of a contract is not strongly implicated here because of the serious questions that have been raised about the terms at issue in the MSA and Order Form.

e. Bond

Novotech argues that the Court should not require a bond because (1) SureClinical will not suffer any harm from the injunction, (2) Novotech has shown a likelihood of success on the merits, and (3) the injunction is in the public interest. Mot. at 17. If a bond is appropriate, the amount should be nominal. Id. SureClinical contends that a $15 million bond is appropriate because that is the amount it would cost for SureClinical to comply with the injunction. Opp'n at 25.

The Court imposes a $2.7 million bond. The Court has broad discretion to require a bond under Fed. R. Civ. P. 65(c). Johnson v. Couturier, 572 F.3d 1067, 1086 (9th Cir. 2009). That discretion vests the Court with the authority to not require a bond if (1) there is no evidence the party to be enjoined will suffer damages from the injunction or (2) the party requesting the preliminary injunction is likely to succeed on the merits of its claims at trial. Conn. Gen. Life Ins. Co. v. New Images of Beverly Hills, 321 F.3d 878, 882 (9th Cir. 2003). The Court finds that SureClinical has put forth sufficient evidence that it will cost $2.7 million to modify its platform to accommodate Novotech's export requirements. However, in light of the serious questions raised by Novotech regarding the distinction between authorized and unauthorized users on SureClinical's platform as

they relate to the license fees allegedly owed by Novotech, the Court does not require a bond beyond that amount.

III. ORDER

For the reasons set forth above, the Court GRANTS Novotech's motion for preliminary injunction and requires a $2.7 million bond to be posted by Novotech pursuant to Fed. R. Civ. P. 65(c).

IT IS SO ORDERED.

Dated: December 2, 2022

JOHN A. MENDEZ,
SENIOR UNITED STATES DISTRICT JUDGE